Appl. No. : **10/659,941**
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REMARKS

Claims 1-52 are pending in the present application. Applicants have amended Claims 1, 22, and 42 to replace the phrase "wherein said beta-glucan composition has a concentration greater than 15% by weight" with the phrase "wherein said beta-glucan composition has a concentration greater than 16% by weight." Applicants have amended Claims 12-21 to replace the term "supplement" with the term "composition." Applicants maintain that the amendments add no new matter and are fully supported by the specification as originally filed. Support for the amendments can be found, for example, in paragraphs [0023], [0029], [0031], and elsewhere throughout the specification.

Claims 1-52 are presented for examination. Applicants respond below to the specific rejections raised by the Examiner in the Office Action mailed August 28, 2005.

Rejection Under 35 U.S.C. § 102(b)

Klein does not anticipate Claims 1, 3-11, 13-22, 24-32, 34-42, and 44-50

a. Klein does not disclose a concentrated beta-glucan greater than 16% - Claims 1, 3-10, 22, 24-31, 42 and 44-50

The Examiner has maintained the rejection of Claims 1, 3-10, 22, 24-31, 42 and 44-50 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,980,918 to Klein ("Klein"). Regarding Claims 1, 3-10, 22, 24-31, 42 and 44-50 the Examiner states that "Klein discloses applicant's beta-glucan composition comprising a glucan having a mixed β(1,3)(1,4) linked glucopyranosyl backbone, wherein [the] beta-glucan concentration [is] about 0.5-15% by weight." *Office Action* at 2. According to the Examiner, compositions of beta-glucan having a concentration of greater than 15%, including 16% read on Klein's composition.

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See, Hybritech, Inc. v. Monoclonal Antibodies, Inc.* 802 F.2d 1367, 1379 (Fed. Cir. 1986). Solely in the interest of advancing prosecution of the instant application Applicants have amended Claims 1, 22, and 42 to recite "greater than 16%," thereby addressing the Examiner's concern that "greater than 15%" reads on "about 0.5-15%." Klein does not disclose a beta-glucan of greater than 16% concentration. Therefore Klein cannot anticipate Claims 1, 22, or 42, or claims that depend therefrom (*i.e.*, rejected claims 3-10, 22, 24-31, 42,

and 44-50). Applicants respectfully request that the Examiner withdraw the rejection of Claims 1, 3-10, 22, 24-31, 42 and 44-50 under 35 U.S.C. §102(b) over Klein.

b. Klein does not disclose a composition packaged and labeled as a dietary supplement - Claims 11, 13-21

The Examiner has maintained that Klein anticipates Claims 11 and 13-19, which are drawn to a composition for reducing low density lipoprotein and total serum cholesterol. According to the Examiner, "[Applicants'] recited dietary supplement composition does not recite any ingredient or substance that renders it different from Klein's composition. . .the said packaging, labeling and the intended use of the composition does not add to the patentability of the composition." *Office Action* at 4. Applicants disagree.

As discussed above, in order to be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. Claims 11 and 13-19 recite "a composition. . . wherein said composition is packaged and labeled as a dietary supplement." As an element of Claims 11 and 13-19, the packaging and labeling must be present in the cited reference in order for that reference to anticipate Claims 11 and 13-19. By stating "the said packaging [and] labeling. . .does not add to the patentability of the composition," the Examiner is failing to give sufficient weight to each limitation of the rejected claims. The Examiner summarily dismissed this limitation without providing Applicants with a legal basis for failing to accord the claim limitation its proper weight. Applicants urge that the dismissal of the claim limitation is improper. As properly construed, Klein fails to teach each and every limitation of the claims. Applicants thus respectfully request that the Examiner reconsider and withdraw the rejection of Claims 11 and 13-19 under 35 U.S.C. §102(b) over Klein.

c. Klein does not disclose a composition prepared by combining a concentrated (1,3)(1,4) beta glucan with a food product- Claims 32 and 34-41

The Examiner also argues that Claims 32 and 34-41are product by process claims which are anticipated by Klein. Claim 32 and dependent claims 34-41 recite "[a] composition prepared by combining a concentrated [] beta glucan [] with a food product. . ." According to the Examiner, the Klein composition is also in combination with a food (oats), as evidenced by Col. 3, lines 23-28 of Klein. Applicants respectfully disagree.

As correctly stated by the Examiner, "product by process claims are [] limited by the structure implied by the steps." M.P.E.P. §2113. Applicants maintain that the composition of Claims 32 and 34-41, which are prepared by combining a concentrated (1,3)(1,4) β glucan having a mixed β(1,3)(1,4) linked glucopyranosyl backbone with a food product" is inherently different from the composition of Klein. In particular, Klein states that cereal-derived beta glucan (CDG) comprises about 3-4% of oat and barley grains. Col. 3, lines 23-28. From this, the Examiner concludes that the composition of Klein is a combination with a food product. Applicants maintain that the Examiner has misinterpreted the teachings of Klein. Col. 3, lines 23-28 of Klein represents a discussion of the **source** from which cereal-**derived** beta glucan (CDG) used in the Klein composition is derived. Col. 3, lines 23-28 do not in any way indicate that the composition of Klein contains 3-4% of oat and barley grains. Applicants refer the Examiner to Figures 1-3 of Klein, which depict the differing chemical structures of beta-glucan derived from microbes (Fig's 1 and 2) and CDG (Fig. 3), such as the CDG present in the Klein composition. When the Klein reference refers to CDG, it is understood that the reference is to a composition having the structure of Figure 3, and not to any combination of CDG with a food product. In short, Klein does not disclose a composition having the same structure as a composition made by combining a concentrated beta-glucan (*e.g.*, the beta-glucan shown in Fig. 3) with a food product. Applicants therefore respectfully request that the Examiner withdraw the rejection of Claims 32 and 34-41 under 35 U.S.C. §102(b) over Klein.

c. The source of beta-glucan influences the chemical composition of the beta-glucan- Claims 9, 20, 31, 41 and 51

Regarding Claims 9, 20, 31, 41 and 51, which each recite the limitation "wherein said beta-glucan is selected from those obtainable from oats, barley, wheat, rye, corn rice, sorghum, millet, or amaranth," the Examiner argues that the source of the beta-glucan does not add to the patentability of the composition and further does not limit the composition. Applicants disagree.

Applicants submit that there are several sources of beta-glucan, such as oats, bacteria, and yeast. See, e.g., Klein, Col. 1, lines 14-16. As discussed in Klein, Col. 1, links 18-22, "the mixed linkage glucan polymers found in cereals are quite different from yeast-derived and bacteria-derived polymers. . .Glucans derived from cereal grains. . .have (1,3) and (1,) linkages and generally have a linear or kinked linear chain." In other words, beta-glucans are structurally

diverse, with their particular chemical structure being dependent upon their source. The source of beta-glucan therefore provides distinguishing characteristics of the beta-glucan polymer. The Examiner has failed to provide Applicants with a basis for rejecting the claim limitation relating to the source of the beta glucan as a limitation of Claims 9, 20, 31, 41 and 51. Applicants respectfully submit that the rejection of Claims 9, 20, 31, 41, and 51 under 35 U.S.C. §102(b) is improper for the reasons set forth above and in the preceding sections of Applicants' response, and request that the Examiner withdraw the rejection.

Claims 1-21 and 32-50 are not anticipated by Wang, et al.

The Examiner has maintained the rejection of Claims 1-21 and 32-50 under 35 U.S.C. §102(b) over U.S. Patent No. 5,512,287 to Wang et al. ("Wang"). Again, the Examiner argues that Claims 1-21 and 32-50 are product by process claims that are only limited by the structure implied by the process, and that therefore the claims are anticipated by the teachings of Wang. For the reasons set forth below, Applicants disagree.

As discussed above, the Examiner has correctly stated "product by process claims are [] limited by the structure implied by the steps." M.P.E.P. §2113. Applicants' claims relate to compositions of beta-glucan that have been "prepared in an alcohol-free process in the absence of organic solvents." By contrast, the beta-glucan compositions disclosed in Wang are recovered by "precipitat[ion] and dehydrat[ion] with alcohol." Wang, Abstract. Applicants submit herewith a Declaration under 37 C.F.R. §1.132 of Richard C. Potter, Ph.D., an expert in the field of polymer chemistry, with several years experience in the extraction of beta-glucans from cereals such as oats. Dr. Potter testifies that precipitation of beta-glucan from an aqueous solution has typically involved the use of large amounts of alcohol, such as isopropanol. The beta-glucan that is the end product of manufacturing processes using alcohol precipitation is inherently chemically and physically distinct from beta-glucan that is the end product of alcohol-free manufacturing processes. According to Dr. Potter:

> [L]onger chains of an unbranched polymer are less soluble than shorter chains in any given solvent. Accordingly, when alcohol is combined with an aqueous solution of beta-glucan, the least soluble chains are preferentially precipitated (corresponding to higher molecular weight chains), [and] the most soluble (i.e., lower molecular weight) chains remain in solution. Thus, it is clear that only a portion of the dissolved beta-glucan (corresponding to the higher molecular weight chains) will be precipitated in alcohol. As such, the beta-glucan

> recovered from alcohol precipitation does not exhibit the range of chain length seen in beta-glucan that has not been precipitated by alcohol.
>
> The partitioning of beta-glucan which arises as a result of alcohol precipitation means that its molecular weight distribution and, therefore, its chemical, physical, and biological properties will differ from beta-glucan which has not been precipitated in alcohol. The molecular weight of alcohol-precipitated beta-glucan will always be biased toward a higher range. Beta-glucan which remains in solution or is fully recovered by other means in solid form will, of course, retain the full range of polydisperse beta-glucan molecules and their associated properties. Accordingly, the concentrated beta-glucan claimed in the present application represents a full range of molecular weight, whereas the beta-glucan recovered from a process involving alcohol precipitation such as that described in Wang et al (U.S. 5,512,287) represents only a truncated range of molecular weight.
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> Potter Decl. ¶¶ 8-9.

The structure implied by the steps of preparing a concentrated beta-glucan in an alcohol-free process versus a process that uses alcohol precipitation is different. Applicants' claimed compositions thus differ from the composition of Wang, which uses an alcohol precipitation step. See, Wang, Abstract. Accordingly, Wang does not anticipate Claims 1-21 and 32-50, and Applicants therefore respectfully request that the Examiner withdraw the rejection under 35 U.S.C. §102(b) over Wang.

Applicants further submit that Wang does not disclose a composition packaged and labeled as a dietary supplement, as recited in Claims 11-21. As discussed above, the packaging and labeling as a dietary supplement is a proper limitation to the claims, and thus must be present in the cited reference in order for the reference to be anticipatory. Wang is silent as to packaging and labeling of beta-glucan, and therefore cannot anticipate Claims 11-21.

Finally, Applicants submit that Wang does not disclose a composition produced by combining beta-glucan with a food product. According to the Examiner, as the beta-glucan in Wang is extracted from oats, the composition is "in combination with a food." *Office Action* at 8. As with Klein, Wang discloses a method of isolating beta-glucan from oats. Thus, the oats are not part of the concentrated beta-glucan of Wang. Nowhere does Wang mention combining the isolated beta-glucan with a food. For the same reasons that Klein does not teach a composition of concentrated beta-glucan with food, Wang fails to do so as well. Accordingly, Applicants submit that Wang cannot anticipate Claims 32-41.

In view of the foregoing, Applicants maintain that Wang fails to teach each and every limitation of Claims 1-21 and 32-50. Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 102(b) over Wang.

Rejection Under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 1-50 as allegedly being unpatentably obvious over Klein. The Examiner notes that Klein only discloses a composition containing 0.5-15% beta-glucan whereas dependent Claims 12, 33, and 43 are drawn to compositions wherein the concentration of beta-glucan is greater than 68%. Nevertheless, the Examiner argues that "it would have been obvious to prepare Klein's beta glucan compositions. . .of different percent concentration to be used for healing burns. . .based on factors like severity of burns." *Office Action* at 10. Applicants disagree.

To establish a *prima facie* case of obviousness, the Examiner must provide evidence that there is some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success found in the prior art. Finally, the prior art must teach or suggest all of the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Applicants maintain that the Examiner has failed to meet the burden of establishing a *prima facie* case of obviousness. In particular, the Examiner has failed to provide any evidence or support for the proposition that the skilled artisan, upon reading Klein, would be motivated to increase the concentration of beta-glucan from 0.5-15% to greater than 68%. Klein teaches that in addition to cereal-derived β-D-glucan, the components of the formulation include several other ingredients, such as an ointment base, a solvent, a plasticizer, a humectant, a suspending or viscosity enhancement agent, an emulsifying or solubilizing agent or agents, a stiffening agent, and an antimicrobial agent. Klein discloses an exemplary formulation in which the relative amounts of each ingredient has been determined and are expressed as a range. See, Klein, Col. 4, lines 19-65, Claim 1. Notably, the range disclosed in Klein is 0-.5-15%, but each and every working example in Klein has a concentration of beta-glucan of merely 2%. The skilled artisan would not, upon reading Klein, thus be motivated to more than quadruple the highest range of beta-glucan recited in Klein to a concentration greater than 68%, particularly in light of the fact

that the working examples teach concentrations of merely 2% beta-glucan. The skilled artisan is familiar with the fact that compositions are typically formulated to maximize benefits while minimizing adverse side effects. In view of the above, Applicants maintain that the Examiner's conclusory statement that one having ordinary skill in the art would have been motivated to alter the balance of ingredients in the Klein composition to more than quadruple the amount of beta-glucan, is not sufficient to establish a motivation to modify the reference.

Furthermore, the skilled artisan would have no reasonable expectation of successfully altering the Klein composition such that the beta-glucan concentration is greater than 68%. In fact, it is clear from the disclosure of Klein that the cream must have certain amounts of several ingredients other than beta-glucan, such as plasticizers, viscosity enhancers, stiffening agents, etc., the balance of which the skilled artisan would appreciate has been optimized. The skilled artisan would not conclude that drastically increasing the amount of beta-glucan above the range taught in Klein would improve wound or burn healing, particularly in view of the fact that the working examples contain concentrations of beta-glucan on the lower end of the disclosed range. In other words, the skilled artisian would not have a reasonable expectation of success in modifying the composition of Klein.

The Examiner has thus not met the requirements of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103(a), and Applicants therefore respectfully request withdrawal of the rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application is in condition for allowance. Nevertheless, the Examiner is invited to contact the undersigned at the telephone number appearing below to discuss any remaining issues.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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